REMARKS

The Examiner has rejected Claims 1, 3 through 9 and 11 through 17. Claims 1, 3 through 9 and 11 through 17 are pending.

Rejections under 35 U.S.C. §103:

Claims 1, 3, 6, 9, 11, 14 and 17 have been rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over Yu et al. U.S. Patent No. 5,071,643 in view of Honour et al. U.S. Patent No. 5,529,923 in further view of Veech U.S. Patent No. 6,020,007. Applicants respectfully traverse this rejection for the following reasons. The Examiner argues that Yu teaches a solvent system for acetaminophen comprising polyethylene glycol and hydroxide ions, water, glycerin and polyvinyl pyrrolidone for soft gel encapsulation. The Examiner states that Yu does not teach lactate salt. The Examiner relies on Honour for a "solution composition" with wetting agents such as sodium lactate. The Examiner further argues that Veech teaches that the "l-form" of salts are preferred in "physiological conditions". The Examiner concludes based on these teachings that the use of the l-lactate salt with acetaminophen in a softgel capsule would have been obvious, and concludes that one of ordinary skill in the art would have found the invention to be obvious.

At the onset, Applicants would like to re-introduce Applicants' invention. Difficulties have been encountered with balancing the solubility, concentration per fill volume, chemical compatibility with capsule material, and bioavailability of acetaminophen to accomplish encapsulated dosage forms containing the drug. The relevant overall context of the invention is, therefore, improved encapsulated dosage forms containing solubilized acetaminophen.

Applicants discussed the shortcomings of the Yu reference in the Background section of the specification on pages 2 to 3. Yu teaches solubilizing acetaminophen with hydroxide ions, polyethylene glycol and water. The problem associated with Yu, which is overcome by Applicants' invention, is the degradation of the capsular material by the levels of hydroxide ion source and its effect on the solution pH. The Examiner concedes that this reference fails to teach or suggest a lactate salt in the formulation.

Honour et al. is directed to pharmaceutical applications of a flavobacterium microbial strain. The text relied upon by the Examiner, column 8, lines 56 through 64, for a teaching of "lactate salts" actually pertains to intravenous compositions for administration of the bacterium. The lactate salt is one of the "auxiliary substances" that can be included in the composition for approximating the "physiological conditions" of the blood. Clearly the Examiner has applied a reference that is not even technologically relevant to the field of Applicants' invention, i.e., capsular oral dosage forms containing solubilized acetaminophen. Certainly, one of ordinary skill would not have found the teachings of this reference to be technologically combinable with Yu et al. No rational motivation can be found to combine Yu et al. with Honour et al. to begin with – and the combination would not lead one of ordinary skill in the relevant art even remotely toward Applicants' invention. It is not understood by Applicants why one of ordinary skill would want to use a lactate salt to accommodate an intravenous administration environment in order to solubilize acetaminophen which is not even suggested in the Honour reference. Again, Applicants' invention is directed toward an oral liquid composition as the relevant technology. The position taken by the Examiner is technologically non-sensical.

Veech pertains to electrolyte solutions and fluid therapy. Again, the Examiner

has pulled a compound out of a technologically irrelevant reference and context. In column 2 of the Veech reference, the relevant context of the Veech invention is described, i.e., orally ingested aqueous solutions, parenteral (intravenous) therapy, dialysis, and irrigation therapy. There is no mention of acetaminophen and l-lactate within encapsulated dosage forms. The reference does not even have to do with fill formulations for capsular dosage forms.

The Examiner applied an inappropriate level of hindsight as well as creativity to compile the rejection. Further, the Examiner has failed to present a combination of references which, individually or in combination, fairly teach or suggest Applicants' invention. Based on technological relevance, one of ordinary skill in the pharmaceutical art would not have been motivated to combine the teachings of these references to begin with because pharmaceutical technology is significantly more complicated that "administering a drug".

Accordingly, a combination of teachings which can adequately support a rejection on obviousness grounds has not been established. The Examiner has in effect alleged that one of ordinary would have combined an ingredient of an electrolyte solution for fluid therapy together with an intravenous auxiliary substance for bacteria and with an oral encapsulated solubilized acetaminophen composition to arrive at Applicants' invention. Of course, these references are not properly combinable to one of ordinary skill because they are not even technologically related to the field of Applicants' invention. Logically, there can be non rational or scientifically sound motivation to assemble these references to arrive at the claimed invention.

Given the above references, the claimed invention is not unpatentable within the

proper meaning of 35 U.S.C. §103(a). This rejection should, therefore, be withdrawn.

The Examiner rejected claims 4, 5, 7, 8, 12, 13, 15 and 16 under 35 U.S.C. §103(a) as being unpatentable over Yu et al. U.S. Patent No. 5,071,643 in combination with Honour et al. U.S. Patent No. 5,529,923 in combination with Veech U.S. Patent No. 6,020,007 in combination with Shelley et al. U.S. Patent No. 5,505,961. Applicants respectfully traverse this rejection for the following reasons.

The shortcomings of the Yu, Honour and Veech references have been discussed in Applicants' remarks to the above rejection under 35 U.S.C. §103(a) and are likewise applicable here and repeated herein. The Examiner further relies upon Shelley et al. U.S. Patent No. 5,505,961 for argument that Shelley teaches that "potassium acetate aids in the solubility of acetaminophen". The Examiner concludes that one of ordinary skill in the art would have found the incorporation of potassium acetate into a solvent system for acetaminophen to be obvious and one would have been motivated to do so to aid in the solubility of acetaminophen.

The shortcomings of Shelley et al. are discussed in the Background section of Applicants' specification on page 3. Specifically, the Examiner relies upon Shelley et al. for a teaching of potassium acetate for solubilizing acetaminophen. As explained in the specification, the problem is that while solubilizing desired amounts of acetaminophen the fill volume is relatively large. It is this problem that Applicants' invention addresses and overcomes.

In other words, Applicants' instant invention is an improvement of systems such as those described in Shelley et al. This improvement is qualified with experimental data on pages 10 through 13, wherein Applicants' have surprisingly struck a balance

that maintains desirable attributes of the fill formulation for encapsulation. Shelley et al. does not teach or suggest l-lactate salts within the solvent system for acetaminophen. The two technologically relevant references applied by the Examiner, i.e., Yu et al. and Shelley et al., even when combined, still do not arrive at the combination of acetaminophen with l-lactate salts. In addition to the inadequacy of the teachings of Yu et al. and Shelley et al. per se, the motivation to combine l-lactate salts with acetaminophen for capsular fill compositions is still absent.

Given the above, the claimed invention is not unpatentable over the cited and applied references within the proper meaning of 35 U.S.C. §103. This rejection should, therefore, be withdrawn.

Conclusion:

In light of the above amendments and the accompanying remarks, it is believed that the application is now in condition for allowance, and prompt notification to that effect is earnestly solicited. The Examiner is invited to contact the undersigned to discuss the application on the merits if it is believed that such discussion would expedite the prosecution.

Respectfully submitted,

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